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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,071	05/24/2001	Bernard R. Neustadt	CN01180K1	6717

24265 7590 12/04/2002

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/04/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/565071

Applicant(s)

Weustadter, Ed

Examiner

J M Ford

Group Art Unit

1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 1/1/72 2002
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1--20 is/are pending in the application.
- Of the above claim(s) 11--20 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1--10 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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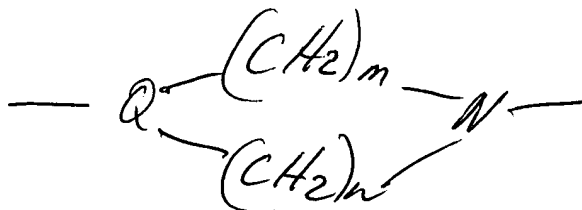
Applicants response of Nov. 7, 2002, is noted.

The claims in the application are claims 1--20.

Applicants elected claims 1--10. Claims 11--14 were restricted out because of the multiple utilities recited in claims 12--14. (MPEP 806.05(h)).

The very large breadth of heteroaryl in claim 1 needs to be reduced to something specific and searchable before claim 11 could be considered as adding back in as claim 11 adds many subclasses in class 514. All CNS diseases in claim 12 could not be considered one utility. Successful results in treating Parkinson's disease (claim 14) is a very sensitive area of utility that would require considerable data.

Claim 1 is very large in its breadth. See Y being



that often controls the search. When claim 1 is put in condition for allowance, consideration will be given to re-combining claim 11, and one specific utility from claims 12--14.

Claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs.

(A) The plural 's' on compounds in line 1 of claim 1 makes the claim read on mixtures, rather than "alternative" one at a time claiming. A compound of the formula:-- is suggested for line 1 of claim 1.

The "heteroaryl" term in **Z** is rejected as unclear and unsupportable.

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Judge Smith found many different definitions for aryl in *In re Sus*, 134 U.S.P.Q. 301, and put some in the footnotes of that decision. Likewise, heteroaryl does not say what is intended. The USPTO only recognizes O, S, N, C, Se and Te as atoms in a hetero ring. While some definitions include B, P and As. It, therefore, becomes necessary for applicants to indicate in the claims what they intend by heteroaryl.

What is the ring size? Is it monocyclic? What hetero atoms are present? How many; where?

Heterocyclic is a huge area of Chemistry, that completely overshadows the nucleus of claim 1.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic reasons for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of the scope of the subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that language is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from the first paragraph of section 112; merits of language in claim must be tested in light of these two requirements.

The heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject <sup>matter</sup> embraced by the claim. The heterocyclic concept is so broad that cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

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The written description is considered inadequate here in the specification. Conception should not be the role of the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1, 3, 4, etc., (7 membered rings) as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heteroaryl applied by applicant, has no idea where the hetero atoms are in this unknown ring,.

What are the hetero atoms?

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Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heteroaryl term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification?

The possible combinations of any number of hetero atoms, in any combination, in multiple size is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is pharmaceutical. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heteroaryl expressions in claim 1 is not acceptable, as it does not indicate, exactly, clearly, and specifically, what heteroaryl ring is being claimed. This expression rests specific conception with the reader, and the specification does not include the source of the starting

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material for the rings which applicant now claims. <sup>a</sup>One must be able to tell from simple reading of the claim what it does and not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. Vs. Binney & Smith Co. 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockheed Aircraft Corp. Vs. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

The heteroaryl expression includes adjacent O/S combination that are unstable. The claimed expression does not tell the reader what the hetero atoms are, or where they are in the ring.

The claim cannot be completely searched, here, until we know what heteroaryl means.

Similarly, the USPTO only recognizes: C,N,O,S,Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heterocyclic.

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Heterocyclic is not just a substituent; it is a whole body of art, larger than the *nucleus* claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, *within* the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1<sup>st</sup> and 2nd paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

Heteroaryl means many different things to different people. Some definitions of heterocyclic include B, P <sup>nd</sup> As as hetero atoms. The U.S.P.T.O. Does not consider those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purposes, it sets forth the prior art, that which applicant found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that ~~stop~~ the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.



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Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

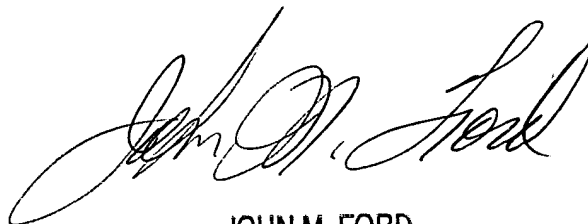
Claims 7 and 9 are, likewise, rejected as a result of the use of heteroaryl, for the reasons noted in the rejection of claim 1.

Claims 2--10 are rejected as being dependent on a rejected claim.

Claims 11--20 stand withdrawn, as being directed to non-elected subject matter under 37 CFR 1.142(b).

John M. Ford:jmr

December 2, 2002



JOHN M. FORD  
PRIMARY EXAMINER  
GROUP     ART UNIT 1624